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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/699,751 | 11/03/2003 | Nigel Maurice Harford | B45053X1D1C3 | 4252 |

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| EXAMINER | |
|---|---|
| MCGAW, MICHAEL M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/699,751 | HARFORD ET AL. | |
| | Examiner | Art Unit | |
| | Michael M. McGaw | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11/03/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *9-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-20* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-8 were cancelled and claims 9-20 were added by preliminary amendment. Claims 9-20 are pending and under examination.

### *Priority*

It is noted that this application appears to claim subject matter disclosed in prior Application No. 10/213,965, filed August 7, 2002. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. **Also, the current status of all nonprovisional parent applications referenced should be included.**

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months

from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 08/649,654 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be made in this application. In making such claim, applicant may simply identify the application containing the priority papers.

### *Claim Objections*

Claim 11 is objected to because of the following informalities: The claim should end with a period. (See 608.01(m)) Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 11, and 13 recite a "substantially homogenous immunogenic Jeryl-Lynn isolate..." The phrase "substantially homogenous immunogenic" is relative terminology that would not allow one of ordinary skill in the art to ascertain what is encompassed within the metes and bounds of the claim. When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. (See MPEP 2173.05(b))

In the present application the specification fails to provide a standard for measuring the term of degree. On page 2, lines 22-25, the specification provides "[b]y substantially homogenous it is meant that the isolate is not contaminated with more than 10%, and preferably less than 5% and most preferably less than 1 % of another Jeryl-Lynn isolate as determined by the sequence of the region set forth above."

The phrase outlined above is subject to a number of interpretations for a few reasons. First, examiner reads the phrase above to mean that the contamination amounts to 10% or less of the population. As to either 5% or 1%, these merely represent non-limiting ideals. Moreover, applicant indicates the difficulty of establishing the degree of homogeneity when it was stated in reference to the MumpsVax on page 2 of the specification that "it is difficult to assess the proportion of the two variants in any given batch of vaccine." If this is true, then how can one say with any confidence whether or not one possesses a substantially homogeneous Jeryl-Lynn isolate?

Second, it is not clear how one tests for homogeneity of the vaccine. In particular, what method would one use to determine that any given Jeryl-Lynn isolate is not contaminated with more than a certain percentage of another Jeryl-Lynn isolate.

Lastly, it is not clear whether applicant is limiting his Jeryl-Lynn isolate to the JL-1 strain or whether the substantially homogeneous immunogenic Jeryl-Lynn isolate could be JL-2 or JL-5 as well. The phrase "of another Jeryl-Lynn isolate as determined by the sequence of the region set forth above" could be read limit the contaminate to not being the JL-1 strain, but does not necessarily limit the predominate species to being JL-1.

If applicant is not limiting his isolate to JL-1 another issue arises. A number of studies have looked at the properties of other Jeryl-Lynn vaccine strains. Most importantly, Afzal, et al. reported the presence of two distinct isolates, JL-2 and JL-5, in the Jeryl Lynn vaccine strain of mumps virus ("MumpsVax"). Afzal examined four vaccine bulks supplied by the manufacturer and found JL-2 in none of two clones, one of five clones, one of two clones and one of eight clones from each of the four

respective vaccine bulks. (See Afzal, pg. 919) Overall, JL-2 represented three of the eighteen clones examined, yielding 16.7% homogeneity of JL-2 in the MumpsVax strain, while evidencing a great deal of variability from lot to lot. The problem is that these numbers are so small that they would not be considered significant. The point of all this being that it is arguable that JL-5 of MumpsVax is also a "substantially homogenous immunogenic Jeryl-Lynn isolate" based upon applicant's criteria and the variability applicant indicates is exhibited by the MumpsVax. Furthermore, applicant indicates on page 2 of the specification that upon further passage there is no guarantee that the balance between JL-2 and JL-5 will be maintained. Afzal has also indicated that certain host cell lines have the tendency to select for variants which could perturb the balance upon passage. In summary, examiner considers that MumpsVax may also be a substantially homogeneous Jeryl-Lynn isolate.

For the aforementioned reasons it is not clear what is meant by the term a "substantially homogenous immunogenic Jeryl-Lynn isolate..." as recited in claims 9, 11, and 13. The specification fails to provide sufficient guidance for measuring this term, rendering this claim, as well as all dependent claims relying on this claim, indefinite.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-13 of U.S. Patent No. 6,656,476 B2 and claims 1-20 of U.S. Patent o. 6,024,962. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '476 patent anticipates the instant combinations as recited in claims 9-20 of the present application. Therefore, the instant claims are not patentably distinct from '476.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael M. McGaw whose telephone number is (571) 272-2902. The examiner can normally be reached on Monday through Friday from 8 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

M. McGaw
6/14/2004

JAMES HOUSEL 6/14/04
SUPERVISORY PATENT EXAMINER
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